2002, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to polypeptides that are capable of binding to one or more of MORT-1 and MACH and which have the amino acid sequence of a G1 protein isoform whose sequence is that of SEQ ID NO:2 or 4. The invention also relates to fragments, analogs and derivatives of such polypeptide, as well as DNA sequences which encode such polypeptide. Vectors comprising such DNA sequences, host cells containing such vectors and methods of producing the polypeptide by growing such host cells are also part of the present invention, as are pharmaceutical compositions and methods for the modulation of cell death or inflammatory processes by introducing such polypeptide into cells.

The interview among Examiners Whiteman and Nguyen and the undersigned attorney conducted on October 23, 2002, is hereby gratefully acknowledged. As a result of this interview, agreement was reached on how the claims could be amended to obviate the 35 U.S.C. §112, second paragraph, rejection. The examiners further agreed that the requirement as to the timing of drawing corrections is not applicable to this case and would be withdrawn. The examiners further agreed that the 35 U.S.C. §112, first paragraph, rejection would be withdrawn, at least for claim 57. Examiner Nguyen also advised that, if claim 44(c) were amended to delete the term "substitution," this would overcome the 35 U.S.C. §112, first paragraph, rejection

of claim 44. As to the interference issues, the examiners agreed to submit the issues to an interference specialist in Group 1600 to determine whether the allowability of claim 57 (other than the 35 U.S.C. §102(e) rejection), which claim overlaps with the claims of Shu, warrants institution of an interference proceeding in light of the request for interference under 37 C.F.R. §1.607 filed on May 9, 2002, which includes at page 4 a statement under 37 C.F.R. §1.608(a). The arguments presented at the interview are substantially set forth herein.

The examiner has refused applicants' traversal of the restriction requirement and maintains claims 60 and 61 as being withdrawn from further consideration. The examiner states that the first product set forth in the originally-filed claims was directed to a DNA sequence encoding a protein and the first method was a method of DNA therapy and not a method of protein therapy. Therefore, the examiner considers that claims directed to protein therapy to be non-elected because they are directed to a second method of using a claimed product not listed in the first claim. This restriction requirement is still respectfully traversed, and applicants reserve the opportunity to petition thereon.

The examiner quotes 37 C.F.R. §1.475(d). It refers to "the first invention of the category". In the category of products, there is only one invention, which includes the DNA sequence and the protein. Thus, it is incorrect to state that the first invention of the category is the DNA sequence. The

protein sequence and the DNA sequence share the same special technical feature and, thus, both comprise the first invention. There is no second invention as there is no non-elected product. The second category mentioned in the claims is the process of use. The first claim directed to a method of use was claim 16. The method of claim 16 is a generic method that specifies that the modulation of cell death or inflammatory processes can be accomplished either by treating with the protein or by introducing the DNA sequence into the cells in order for the cells to make the protein. Indeed, the first species mentioned in claim 16 is the protein therapy species. The entire scope of claims 60 and 61, as presented on September 17, 2001, should have been examined as there is no grounds to divide up such a generic claim. In any event, if the examiner intended to examine only one of protein therapy or DNA therapy in view of the fact that they both appeared in the same claim, either the examiner should have examined protein therapy as it was mentioned first, or applicants should have been given the choice of which to be examined first. The election of DNA and protein as the invention of the first category does not require that use of either one of the two be examined first when they are both present in the same claim. Thus, applicants' election of protein therapy should have been accommodated. Reconsideration and withdrawal of the restriction requirement are again respectfully urged.

The examiner points out that a PTO-498 relating to drawing requirements was filed with the non-final rejection

Paper No. 10 and that, if the reply to the final rejection does not have a response to the 498, the response will be considered non-responsive in accordance with 37 C.F.R. §1.85(a). This requirement is respectfully traversed.

The present application was filed November 29, 1999. Thus, the portion of 37 C.F.R. §1.85(a) relied upon by the examiner is not applicable to this case. That rule is applicable only to applications filed after November 28, 2000. Accordingly, the present application is subject to the information on how to effect drawing changes set forth on the back of the 498 form itself, which indicates that the drawing corrections can be made after the Notice of Allowance is issued. Accordingly, it is respectfully requested that the requirement to file the drawing corrections in reply to the final rejection be withdrawn and that the timing set forth on the back of the PTO-498 be reinstated. At the interview, the examiners agreed to do so.

Claims 44(c), 49-53, 54(c), 57 and 59 have been rejected under 35 U.S.C. §112, first paragraph, because the specification does not reasonably provide enablement for the full scope of these claims, particularly with respect to paragraph (c) of claims 44 and 54. This rejection is respectfully traversed.

First of all, it is noted that the examiner states that the claims require that the analogs affect the intracellular signaling process initiated by the binding of FAS ligand to FAS-R or the binding of TNF to p55-R. However, the

examiner's attention is invited to the fact that this language has been deleted from all of the present claims. The claims only now require binding of the analog to one or more of MORT-1 and MACH. Binding tests can be routinely run quickly and in great quantities. It does not involve undue experimentation to make random mutations of a DNA sequence so as to affect up to ten amino acids and then assess all of the randomly-generated polypeptides produced by such mutated clones for their ability to bind to MORT-1 and MACH. The polypeptides still must retain at least 95% identity, and so it is not unreasonable to expect each one to have the binding properties. Thus, no experimentation is necessary at all. However, to the extent that one would want to double-check the capability to bind, this can readily be done with standard techniques. It should be noted that in the *Wands* case cited by the examiner relating to monoclonal antibodies, the Board held that the claims complied with the first paragraph of 35 U.S.C. §112 despite the extensive experimentation involved in making monoclonal antibodies. Doing a simple binding assay would involve no more experimentation than was approved in *Wands*. Reconsideration and withdrawal of this rejection are, therefore, respectfully urged.

It is noted that in the interview the examiners agreed that this rejection would be withdrawn with respect to claim 57, which includes only a single substitution. Furthermore, the examiners indicated that if claim 44(c) were amended to delete reference to substitutions, claim 44 would

then be allowable. Applicants' attorney informed the examiners that applicants believed strongly that it would not take undue experimentation to determine if any given analog, having no more than ten changes in the amino acid sequence (i.e., retaining at least 95% identity), would bind to MORT-1 and MACH and, therefore, applicants desired to retain the option of appealing this last remaining part of the rejection. The examiners indicated, however, that applicants could submit an additional claim without "substitution" in claim 44(c) as this claim would be in condition for allowance and would serve to crystallize the issues.

Accordingly, new dependent claims 69-71 have now been added, all of which would be free of the 35 U.S.C. §112, first paragraph, rejection. Claim 69 is dependent from claim 44 and specifies that the sequence of (c) does not involve substitutions. Claim 70 is dependent from claim 54 and has the same provision. Claim 71 is dependent from claim 44 and is otherwise the same as claim 57, which the examiners indicated is free of the 35 U.S.C. §112, first paragraph, rejection.

Accordingly, reconsideration and withdrawal of this rejection, at least with respect to claims 57 and 69-71, are respectfully urged.

Claims 49-52, 59 and 66 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. With respect to claim 49, the examiner states that the claim does not point out which molecule "a molecule in accordance with claim 44" is referring to in the claim. With respect to claims

50-52 and 66, the examiner states that the claims are indefinite because they do not point out which molecule "a vector in accordance with claim 49 (65)" is referring to in the claim, and claim 59 is indefinite because it does not point out which polypeptide "a polypeptide in accordance with claim 54" is referring to in the claim.

In order to obviate this rejection, agreement was reached in the interview that the language "a molecule" or "a vector" in the body of the claim (not the first word of the preamble) would be changed from "a" to "the" in order to obviate this rejection. Accordingly, claims 49, 52, 59, 65 and 66 have been so amended. It is not understood why claims 50 and 51 are included in this rejection as they do not have the language quoted by the examiner in the rejection. In view of this amendment, it is believed that the entire rejection has now been obviated. Reconsideration and withdrawal thereof are, therefore, respectfully urged.

Claims 44(b, c), 49-53, 54(b, c) and 57 have been rejected under 35 U.S.C. §102(e) as being anticipated by Shu et al. The examiner states that Shu claims an isolated Casper protein, which anticipates the proteins claimed in the present claims.

It is applicants' position that applicants can prove that applicants' invention was made prior to Shu's invention and, therefore, the rejection under 35 U.S.C. §102(e) must be withdrawn because it only provides that a patent can be prior art when it was granted before the invention by the applicant.

Ordinarily, applicant would file a declaration under 37 C.F.R. §1.131 to overcome this rejection. However, MPEP §715.05 clearly states that when the reference in question is a non-commonly owned U.S. patent claiming the same invention as applicant and its publication date is less than one year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be way of 37 C.F.R. §1.608 instead of 37 C.F.R. §1.131. Applicants filed the appropriate statement under 37 C.F.R. §1.608(a) on May 9, 2002. Accordingly, the rejection must be withdrawn and the application forwarded for institution of an interference proceeding.

If the examiner believes that any of the rejected claims are not directed to the same invention as is claimed in Shu, having regard to the definition of "same patentable invention" defined in 37 C.F.R. §1.601(n) (see MPEP §715.05), then it is requested that applicants be advised which claims are being rejected solely on the specification of Shu, and applicants will file an appropriate declaration under 37 C.F.R. §1.131 in order to obviate the rejection for those claims. However, as the rejection refers only to what is claimed by Shu, it is assumed that all of the rejected claims are considered to be directed to the same patentable invention as the claims of Shu so that 37 C.F.R. §1.608 can be used to overcome the rejection of all of the claims. In view of the filing of the request for an interference under 37 C.F.R. §1.607, including the required statement under 37 C.F.R.

§1.608(a), it is again requested that this case be forwarded for institution of an interference.

The examiner states that MPEP §2307.02(b) states that an interference cannot be considered if grounds of rejection remain. However, this section of the MPEP does not refer to a §102(e) rejection over the interfering patent; it refers only to any other remaining rejections. A claim must be patentable in order to enter an interference. However, the patentability of the claim over the interfering patent is the purpose of the interference. The only way to overcome the rejection is to have an interference. Accordingly, it is urged that the examiner is misreading MPEP §2307.02. The examiner also refers to MPEP §706.02(b). However, this paragraph of the MPEP clearly states:

> When the claims of the reference and the application are directed to the same invention or are obvious variants, an affidavit or declaration under 37 CFR 1.131 is not an acceptable method of overcoming the rejection. Under these circumstances, the examiner must determine whether a double patenting rejection or interference is appropriate. ... If there is no common assignee or inventor and the rejection under 35 USC 102(e) is the only possible rejection, the examiner must determine whether an interference should be declared. [emphasis added]

Certainly, this language clarifies MPEP §2307.0(b) as referring only to rejections other than the 35 U.S.C. §102(e) rejection.

The examiner states that 37 C.F.R. §1.608(a) is not applicable because the examiner cannot consider applicants' priority date, citing MPEP §2308.01. However, as pointed out in the interview, the quoted portion of MPEP §2308.01 refers

only to the patent's effective filing date not being considered. It is silent as to consideration of the application's priority date. 37 C.F.R. §1.608(a) clearly refers to the effective filing date of the application. For the present application, which has an English-language priority document of record, the examiner can readily determine what the effective filing date of the application is. If applicants' claims are entitled to the effective filing date of the priority application, then that is the date which must be considered under 37 C.F.R. §1.608(a). In the course of the interview, the examiner agreed to submit this issue to the interference specialist for final resolution.

For all of these reasons, it is urged that the present application is now in appropriate condition for institution of an interference proceeding. At least claim 57 is directed to the same invention as is claimed in Shu and is not subject to any rejection other than the rejection under 35 U.S.C. §102(e). An interference must be declared to determine priority of claim 57. Any rejections remaining on the other claims can be held in abeyance pending completion of the interference proceeding. *Ex parte* prosecution with respect to the remaining claims is suspended pursuant to 37 C.F.R. §1.615. Reference is made to MPEP §2307.02, where it states:

> If at least one of the presented claims is not rejectable on any such ground and is claiming the same invention as at least one claim of the patent, the examiner should proceed to propose an interference. [emphasis added]

MPEP §2309 states that an applicant seeking to have an interference declared may facilitate the examiner's proposal of an interference by providing as much of the material referred to therein as possible in a convenient form, e.g., providing certified copies of the foreign benefit documents and clean copies of the involved claims. At the interview, the examiner indicated that certified copies of the priority documents were in the file. Nevertheless, a courtesy photocopy of the first priority document can be provided to the examiner upon request. Attached hereto is a clean copy of claims 44, 49, 50, 51, 52, 53, 54 and 57, as well as new claim 71, which are believed to be all of the initially involved claims. As new claims 69 and 70 do not overlap with the claims of Shu, it is not certain if the examiner considers them to be directed to the same patentable invention as in the claims of Shu. However, as claims 47 and 58 were not included in the rejection, it is assumed that claims 69 and 70 would not be included in the rejection. If there is anything else that applicants can do to facilitate the examiner's preparation of the interference papers, applicants would be happy to comply, and the examiner is encouraged to contact the undersigned attorney in this regard.

It is submitted that all of the claims now present in this case fully comply with 35 U.S.C. §112 and clearly define over all references of record other than Shu. In view of the fact that Shu claims the same invention as being claimed by applicants in some of applicants' claims, this case is now in

condition for declaration of an interference. Reconsideration and withdrawal of all of the present rejections and passage of the present application to the Interference Branch are, therefore, earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By _____
Roger L. Browdy
Registration No. 25,618

RLB:rd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
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Version with Markings to Show Changes Made

In the Claims

Claims 49, 52, 59, 65 and 66 have been amended as follows:

49 (~~New~~Amended). A vector comprising ~~a~~ the molecule in accordance with claim 44.

52 (Amended~~New~~). Transformed host cells containing the~~a~~ vector in accordance with claim 49.

59 (~~New~~Amended). A pharmaceutical composition for the modulation of the FAS-R ligand- or TNF-effect on cells comprising, as active ingredient, ~~a~~ the polypeptide according to claim 54.

65 (Amended~~New~~). A vector comprising the~~a~~ molecule in accordance with claim 63.

66 (Amended~~New~~). Transformed host cells containing the~~a~~ vector in accordance with claim 65.

New claims 69-71 have been added.